

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Date: April 18, 2002

Memorandum

SUBJECT: Response to Comments from Sipcam Agro USA, Inc. On the EPA's January 18, 2001 "Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document " and the January 19, 2001 "Atrazine: HED's Revised Preliminary Human Health Risk Assessment for the Reregistration Eligibility Decision"; April 12, 2001

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PC Code: Atrazine 080803

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In response to the HED's Revised Preliminary Human Health Risk Assessment for atrazine, Sipcam Agro USA, Inc., provided the Agency with a cogent, well-organized document which included considerable supportive information. This memorandum considers the points taken as a whole, together with the documentation provided by Sipcam Agro USA, Inc. Therefore the HED response will address each of the unique comments or issues raised and related comments at the same time.

Response to Comment Section 1: Referring to the EPA's review of study MRID 449580-01, Determination of Transferable Residues on Turf Treated with Atrazine.

[Section numbers used match those in the document submitted by Sipcam Agro USA, Inc.]

1.1

1.1.1 The Agency agrees that the two geographically distinct test sites were within the typical area of use for the atrazine turf product, since northern grasses are harmed by atrazine. Note that another, granular turf residue study [MRID 449588-01] performed by Novartis Crop Protection, selected Florida as one of the two test sites. Because of its' unique climate, selection of Florida as one site was useful for geographic diversity.

1.1.2 The Agency agrees that a second application after 30 days at the reduced rate of 0.4 oz product, per label, probably would not result in higher residues than the single-application methodology actually used.

1.1.3 While the absence of tank mix samples prevents one method of verifying the application rate, the indirect methodology used by verifying active ingredient and spray volume is considered adequately reliable.

1.1.4 The Agency agrees the variation between peaks does not affect the quantitation of residues.

1.1.5 The Agency states that ideally field fortifications should reflect the range of values obtained experimentally, and the registrant agrees. The study data were subsequently corrected by the author, based on the field fortifications.

1.2

1.2.1 This comment, and comments later in the document, relate to an unfortunate propagation of a misstatement in the original study MRID 449580-01. The study report stated, on page 16, that 0.72 oz active ingredient (ai) were applied per 1000 sq ft, which is equivalent to 2 lb ai/acre. It goes on to state that the label rates range from 0.4 to 0.8 oz *ai*/1000 sq ft, which is inaccurate: it should read 0.4-0.8 oz *product*/1000 sq ft. This error was transcribed by the Versar, Inc., reviewers and later by the Agency. It shall be corrected in the updated exposure and risk assessments. The text error did not affect the accuracy of the calculations presented by the Agency.

1.2.2 The clarification is helpful. Residues may transfer more readily if leaves are wet or

moist. Also, dissipation rates may be greater where there is increased moisture, precipitation, or irrigation. Note also that rainfall in Georgia was particularly low during the test, reportedly 7% of normal: so if the turf was wet on DAT 21, there were more residues available to transfer. These clarifications help characterize the range of residues and dissipation patterns, which are quite distinct between the Georgia and North Carolina sites.

- 1.2.3 The text of the EPA risk assessment mistakenly referred to the higher 12 hour residue as being from Georgia when it was from the North Carolina site, however residues for all calculations were correctly identified. Outliers, when properly identified as not fitting into an observed dissipation pattern, may be excluded. However, the highest TTR obtained at 12 hours while turf was still wet can also be used to characterize human contact with wet grass. It is reasonable to assume that residential exposure could occur while turf is wet in southern climates, where dew and rain can keep turf wet much of the day.
- 1.2.4 The Agency agrees that eliminating the sample data taken from wet turf produces a better line-of-fit for the first order regression. See also response 1.2.3.
- 1.3. The Agency will correct the text in the document relating to the label and label rate, as noted in 1.2.1 above.
- 1.4.1 See 1.2.2.
- 1.4.2 See 1.2.2 and 1.2.3.
- 2.1 Comments and responses were covered in 1.1.1, 1.1.2, and 1.1.3.
- 2.21 Comment and response covered in 1.2 and 1.3 above, and corrections to text will be made. The erroneous statement of label rate had no effect on the calculations made by the Agency.
- 2.2.2 As stated in 1.2.3, the Agency will use all of the study residue data to characterize potential exposure to atrazine, whether on wet or dry turf. The range of DAT 0 residues, from an average of 0.21 µg/cm² at both sites (without the highest value) to 1.32 µg/cm² (the highest average TTR), represents a transferable range of 1 to 6 percent of the applied chemical. While the 6% TTR may be based on damp turf, that situation is not unusual for actual residential or recreational exposure. The range of 1 to 6% TTR is fairly representative for transfer of residues, based on data from other chemicals/ dissipation.
- 2.2.3 See response to comment 1.2.2.
- 2.2.4 See response to comment 1.2.4.

- 2.2.5 The MOEs for dermal postapplication exposure were based on the Agency's Residential SOPs, revised as of February, 2001. The TTR from both the average dry and the wet sites were used to develop separate risk estimates, thereby representing a range of potential exposures. There is no reason to believe that residential or recreational exposure to atrazine treated turf could not occur when the turf is wet or damp, particularly as atrazine is used mostly in the Southeastern U.S., where such conditions are prevalent. Therefore, representing the estimated dose and MOE in both dry and wet contact conditions provides a more complete assessment of the range of potential risk.
- 2.2.6 Any aggregation of point estimates is likely to overestimate the potential total dose, and the Agency example is considered a high-end example.
- 2.2.7 See response to comment 2.2.5.
- 2.2.8 See response to comment 2.2.5.
- 3.1.1 See response to comment 2.2.5.
- 3.1.2 See response to comment 2.2.6.
- 3.1.3 The TTR data will be used to estimate exposure to residue transfer from both wet and dry turf. Therefore, there is no need to eliminate the high value, since it has been adequately explained by both the researchers and the Sipcam Agro USA authors.
- 3.2.1 See response to comments 2.2.5 and 3.1.3.
- 3.2.2 The aggregate dose will be presented in the risk assessment if individual route-specific MOEs are not of concern.
- 3.2.3 The assumptions are based on the best available scientific studies. Some of the studies used for the assumptions are the closest equivalent to the behavior of interest. Since relevant studies observing children playing on turf or dirt, and measuring their exposure are not available, indoor studies have been used instead. The assumptions and data are regularly reviewed and presented to the Science Advisory Panel for comments and recommendations. The revision to the Residential SOPs states, for contact time:
"This is based on the 75th percentile value (i.e., 120 minutes) for playing on grass for ages 1-4 years and ages 5-11 years (Tsang and Klepeis 1996 as cited on pg. 15-79 of EPA 1997, Exposure Factors Handbook, EFH). The data were truncated at the 75% percentile. 23% of children ages 1-4 years played on grass more than 2 hours/day (p. 15-78). In comparison, the 95th percentile for playing outdoors is 3.5 hours, the 95th percentile for time spent on school grounds/playgrounds is 2.9 hours, while the 95th percentile for time spent at home in the yard or other areas outside the home is 5.75 hours for children 1-4 years (p. 15-96, 15-124 and 15-136 of EPA EFH, 1997).
- 3.2.4 The statements as to aggregate exposures of small children to atrazine will be revised based on the responses above, and decisions of the Hazard Identification Assessment

Review Committee (HIARC).

- 3.2.5 Adult residential postapplication exposures in the atrazine risk assessment will be based upon both the spray and granular turf residue studies and both the wet and dry, irrigated and non-irrigated residues in order to fully characterize the range of potential exposures.